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Pharmaceutical System Strengthening Interventions to Improve Access to Antiretroviral Therapy

October 2014



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SLAPS 
Systems for Improved Access
to Pharmaceuticals and Services

Pharmaceutical System Strengthening Interventions to Improve Access to Antiretroviral Therapy

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This report is made possible by the generous support of the American people through the US Agency for International Development (USAID), under the terms of cooperative agreement number AID-OAA-A-11-00021. The contents are the responsibility of Management Sciences for Health and do not necessarily reflect the views of USAID or the United States Government.

About SIAPS

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

Recommended Citation

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Mabirizi D, Embrey M, Saleeb S, Aboagye Nyame F. *Pharmaceutical System Strengthening Interventions to Improve Access to Antiretroviral Treatment*. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program; Arlington, VA: Management Sciences for Health; 2014.

Key Words

access, antiretrovirals (ARVs), antiretroviral therapy, treatment, HIV and AIDS, pharmaceuticals, strengthening, systems

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ACRONYMS AND ABBREVIATIONS

3TC	lamivudine
AIDS	acquired immunodeficiency syndrome
ART	antiretroviral therapy
ARV	antiretroviral
AZT	zidovudine
CD4	cluster of differentiation 4
EDT	Electronic Dispensing Tool
EFV	efavirenz
HIV	human immunodeficiency virus
LPV/r	lopinavir/ritonavir
mg	milligram
MoH	Ministry of Health
MoHSS	Ministry of Health and Social Services
MSH	Management Sciences for Health
NASCOP	National AIDS and STIs Control Programme (Kenya)
NVP	nevirapine
OI	opportunistic infection
PEPFAR	US President's Emergency Plan for AIDS Relief
QPP	Quantification Procurement and Planning
R	Rand
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SOP	standard operating procedure
SPS	Strengthening Pharmaceutical Systems
Uganda SURE	Securing Ugandans' Right for Essential Medicines
TIPC	Therapeutics Information and Pharmacovigilance Centre
USAID	US Agency for International Development
USD	US dollars
WHO	World Health Organization

PHARMACEUTICAL-RELATED CHALLENGES TO INCREASING ACCESS TO ANTIRETROVIRALS

The world's response to the AIDS pandemic of dramatically increased financial assistance to provide affordable medicines for HIV and AIDS did not automatically lead to *access* to antiretrovirals (ARVs). The effectiveness of these multimillion dollar initiatives was recognized to be limited by the capacity of the health care and pharmaceutical supply systems to deliver these lifesaving medicines. Constraints to improving access to ARVs included inadequate capacity in clinics and hospitals that provide antiretroviral therapy (ART); inadequate pharmaceutical planning and information systems; and an inefficient supply chain.

The United Nations Millennium Project task force concluded that global programs cannot successfully address individual diseases until more resources are devoted to strengthening entire health systems and that the effectiveness of a health system can be measured by the uninterrupted availability of medicines.¹ A holistic approach to access looks beyond product availability and price to include other essential components, such as the availability of quality pharmaceutical services and the ability of the patient to benefit from both products and services that support the safe, effective, and appropriate use of the medicines.

Countries have stepped up to meet this challenge. This paper illustrates pharmaceutical systems' strengthening interventions and their impact on improving access to ARVs and related services as well as continuing challenges and some recommendations.

When Management Sciences for Health (MSH) first started HIV and AIDS–related work in the pharmaceutical sector in 2003 with USAID funding, MSH designed interventions explicitly to help scale up ART programs and increase the number of people accessing ART. The underlying implementation strategy is to improve quality and efficiency in the delivery of ART services through strengthened ART pharmaceutical management systems, and to apply those enhancements to a wider range of medicines and supplies. The key, however, has been to create efficient pharmaceutical and commodity management systems that will be sustained for years to come with the outcome being a stronger pharmaceutical sector that serves not only specific HIV and AIDS–related needs, but *all* health needs.² And because the pharmaceutical system is a large part of the overall health system, by strengthening individual components, the whole system benefits (figure 1).

¹ Ruxin J, Paluzzi J E, Wilson P A, et al. Emerging consensus in HIV/AIDS, malaria, tuberculosis, and access to essential medicines. *Lancet* 2005; 365(9459):618-21.

² Embrey M, Hoos D, Quick J. How AIDS funding strengthens health systems: progress in pharmaceutical management. *J Acquir Immune Defic Syndr*. 2009; 52:S34–S37.



Figure 1. Starting off as parallel clinics, ART clinics have progressively been integrated into routine services, offering a wide array of services thus enhancing access and reducing stigma

Under the rubric of the WHO Framework for Action, *Strengthening Health Systems to Improve Health Outcomes*, the medical products, vaccines, and technologies building block overarches all of MSH's work in this area; however, contributions to health systems strengthening can also be measured across the other five building blocks: service delivery, health workforce, information, financing, and leadership and governance.

MEDICAL PRODUCTS, VACCINES, AND TECHNOLOGIES

Pharmaceuticals, such as ARVs, and other medical products are not merely the beginning of a supply chain, but also are part of the pharmaceutical management framework, which represents the flow of activities that must be coordinated to ensure that appropriate, high-quality medicines are available. The framework emphasizes the cyclic relationships among selection, procurement, distribution, and use activities, all of which are enabled by a strong management support system.³ Each component of the framework depends on the success of the previous component and contributes to the viability of the next. The entire framework relies on policies, laws, and regulations, which, when supported by good governance, sustain the commitment to strengthen pharmaceutical supply systems (figure 2).

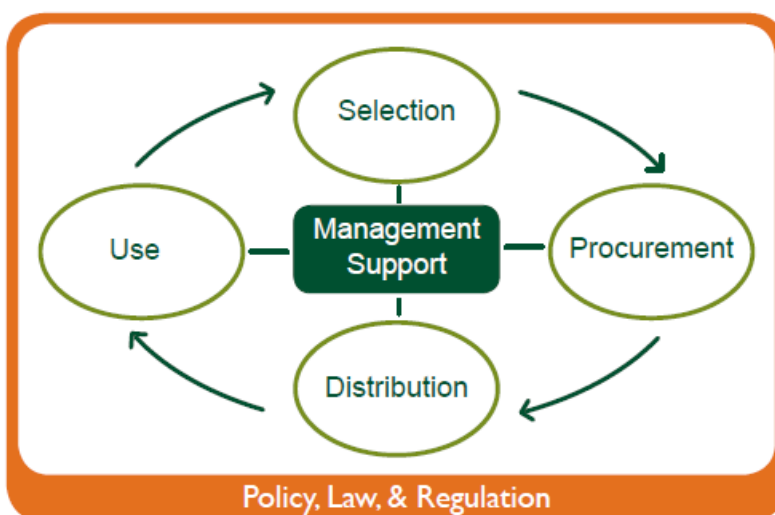


Figure 2. Pharmaceutical management framework

Coordinating and Harmonizing Pharmaceutical Stakeholder Activities

In the rush to get lifesaving ARVs to as many people as possible as quickly as possible, HIV and AIDS supply systems were set up in parallel with primary pharmaceutical supply systems and other vertical systems, such as tuberculosis. In a vertical supply system, all or some of the functions of the pharmaceutical management framework are carried out separately from the primary distribution system. As programs mature, however, countries should work toward integrating HIV/AIDS-related pharmaceuticals into the essential medicines supply system to maximize efficiency. By integrating public health programs and supply systems, countries can continue to scale up while strengthening existing pharmaceutical management systems for long-term sustainability. Incorporating pharmacy and supply services into existing systems also allows programs to leverage resources and share capacity-building costs. Uganda's Ministry of Health

³ MSH. Toward sustainable access to medicines. In: MSH. *MDS-3: Managing Access to Medicines and Health Technologies*. Sterling, VA: Kumarian Press; 2013.

(MoH) is integrating the health commodity supply chains, starting with bringing HIV commodities into the essential medicines supply.⁴ The creation of a web-based system for ordering ARVs has facilitated integration and streamlined ordering and reporting of ART commodities through MoH's centralized health management information system.⁵

Launched in 2010, the Quantification Procurement and Planning (QPP) Unit within Uganda's MoH focuses on coordination, standardization, harmonization, streamlining, and centralization of all central-level activities related to planning for essential medicines and health supplies. In November 2011, during Uganda's negotiations with the Global Fund over new grants, the unit became the central hub for resources and support for evidence-based updates on national quantifications, critical analysis and appraisal of options for meeting country requirements, and harmonization of supply plans.⁶ In addition, the unit identified funding gaps leading to the mobilization of resources from donors and other sources, including USD 6 million for laboratory commodities.⁷

"The role played by the QPP Unit has been lacking in the country. With this unit in place, our coordination on pharmaceuticals has been simplified."

—Caty Falls, Global Fund Country Portfolio Manager for Uganda during country grants negotiations in November 2011

Ministries that develop evidence about what funding is really needed can better advocate for budget increases. Mapping donor investments and providing a forum for cooperation can also generate resources. For example, the Government of Rwanda and USAID created a mechanism for stakeholder collaboration to address multiple, donor-specific ARV distribution systems, which had been operating autonomously. The Coordinated Procurement and Distribution System optimized donor resources, simplified pharmaceutical management, standardized ARVs independent from donor programs, and consolidated multiple supply chains into one. Coordination provided by the new program in its first year simplified ART pharmaceutical management and lowered costs: average treatment costs/patient/month decreased from USD 30 to USD 20, and no medicines procured through the system expired, whereas in the previous year, expired medicines were valued at USD 70,000.⁸ The government then enlarged the coordination to include other HIV-related commodities and additional essential medicines.

National-level coordination remains a significant challenge often with limited communication between AIDS control program managers and supply chain managers. Initially, creating a forum

⁴ Uganda SURE. Annual Progress Report Year 4: October 2012 to September 2013. Kampala: Uganda SURE. 2013.

⁵ AIDS Control Program. Web-based ARV Ordering System (WAOS): problem analysis and consensus-building meeting report. Kampala: ACP; 2014.

⁶ Uganda SURE. Success story: USAID-supported QPP unit gains recognition from partners. Kampala: Uganda SURE; 2012.

⁷ Uganda SURE. Success story: information sharing leads to better availability of vital medicines. Kampala: Uganda SURE; 2013.

⁸ Tarrafeta B, Gabra M, Buki GI, et al. Optimizing resources: the coordinated procurement and distribution system of ARVs in Rwanda. Paper presented at 2006 HIV/AIDS Implementers Meeting, June 12-15, 2006, Durban, South Africa; 2006.

for HIV and AIDS supply stakeholders to review consumption patterns, patient numbers, and ART patterns and using this information to review projections and plans will improve ART service delivery. Eventually, broadening such forums to include all pharmaceutical and supply stakeholders will strengthen the entire pharmaceutical system and facilitate harmonization of the pharmaceutical supply chain.

Decentralizing ART Distribution

A key objective to improving the quality of and access to health system services is bringing those services closer to the community and the patient, which is at the heart of many countries' decentralization policies. Because of a shortage of pharmacists and pharmacy assistants in South Africa, nursing staff must fill the gap in lower level clinics to provide pharmaceutical services. To increase access to ART through a decentralized approach, the government and stakeholders developed a system that refers patients who are stabilized on ART from hospitals down to primary health-care clinics, while still maintaining a centralized dispensing unit at the hospital.⁹ In addition to reducing the patient load for the hospital's pharmaceutical service, this strategy also reduces transportation costs for patients and brings services closer to home. The system worked so well for ART patients in the first six months that it was expanded to include patients needing long-term treatment for mental illnesses and other chronic diseases. This process (illustrated in figure 3) is a good example of how electronic tools can enhance the efficiency and quality of services at decentralized sites, but also can ensure adequate patient tracking and proper record-keeping, both of which are important in monitoring ART.

Designing Useful Monitoring and Evaluation Systems

Together with collection, analysis, and use of ART information, AIDS control programs should develop a set of indicators to regularly monitor program performance and guide strengthening activities—monthly, quarterly, and annually.¹⁰ High-level indicators can measure progress toward achieving national HIV and AIDS strategic plan objectives, such as access. Supply management indicators act as early warnings of stock problems with ARVs and other medicines, so that program managers can act accordingly. Other indicators related to service delivery should include ART adherence, loss to follow-up and patient retention. Ultimately, countries should use an indicator-based monitoring and evaluation system to improve the performance of the entire national pharmaceutical supply system with the goal of integrating the information into the national health information system. SIAPS and SPS have supported Cameroon, Ethiopia, Kenya, and Namibia to use routinely collected patient and commodity data to develop and disseminate monthly, quarterly and annual reports. This information has been used in supply chain decision and guideline development.

⁹ Steel G, Paterson M, Sallet JP. Improving adherence by decentralizing ART to local clinics in South Africa using a computerized pharmacy tool. Paper presented at XVI International AIDS Conference, August 13-18, 2006, Toronto; 2006.

¹⁰ WHO. Harmonized monitoring and evaluation indicators for procurement and supply management systems: early-warning indicators to prevent stock-outs and overstocking of antiretroviral, antituberculosis and antimalaria medicines. Geneva: WHO; 2011. Paper presented at the Third International Conference for Improving Use of Medicines. Antalya, Turkey, November 14-18, 2011.

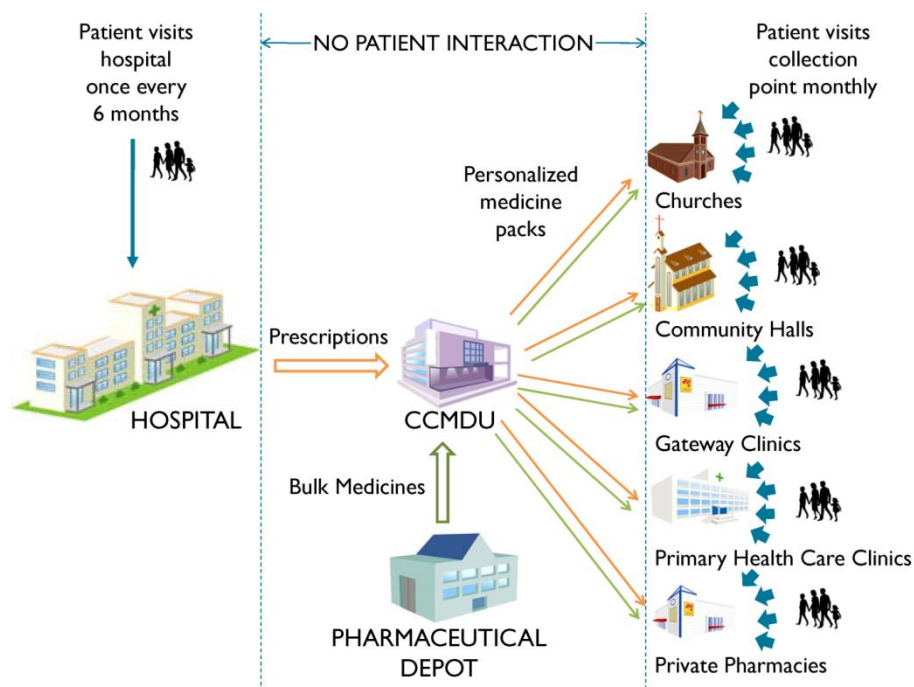


Figure 3. Supporting treatment down-referral in South Africa through a Central Chronic Medicines Dispensing Unit.

Prescriptions for stable patients from two hospitals are sent to the central unit where they are packaged for individual patients and sent to one of 143 community collection points chosen by the patient. Patients receiving medicine at private pharmacies and community halls waited on average less than 30 minutes, whereas patients at hospitals waited more than 4 hours. Over 3 years, the unit increased the number of prescriptions by 80% to reach approximately 86,000 patients per quarter. The Strengthening Pharmaceutical Systems (SPS) Program helped develop policies and procedures for the down-referral system and a computerized dispensing system at the dispensing unit.

PHARMACEUTICAL SERVICE DELIVERY

Improving access to ART and pharmaceutical services is not limited only to assuring product availability; a comprehensive approach strives to ensure that patients receive medications optimized to their clinical needs, in doses that meet their individual requirements, for an adequate time, and at the lowest cost to them and their community. In addition, to ensure services that will result in optimal treatment outcomes, systems should be in place to train health professionals, provide medicine information and counseling on treatment adherence and appropriate use, and formulate policies and regulations for improved pharmaceutical care.

Promoting Patient Safety through Pharmacovigilance

Medicine information and pharmacovigilance are critical because they give health care providers and patients unbiased information on safety and effectiveness of medicines to improve treatment outcomes and guide treatment recommendations. Pharmacovigilance is particularly important when countries approve and use new medicines, such as ARVs to large populations of patients in need of these medicines. Developing countries, however, are hampered by a shortage of both expertise and the capacity needed to build a medicines information and safety system from the ground up. The model for Namibia integrates medicines information and pharmacovigilance activities into one unit to capitalize on the potential synergy between the two aspects of ensuring patient safety to leverage scarce resources. Although the initial purpose of the Therapeutics Information and Pharmacovigilance Centre (TIPC), launched in 2008, was to support HIV and AIDS services, its mandate includes all essential medicines.

An example of how the TIPC has contributed to patient treatment and safety is through its spontaneous reporting system on adverse medicine reactions. Namibia changed the backbone of its recommended first-line ART from stavudine to zidovudine because of concerns about peripheral neuropathy, but lacked local safety data to support the decision. In 2009, TIPC surveillance indicated that zidovudine-associated anemia was the most frequent ARV adverse effect (64%), which contributed to fast-tracking a switch in medication to a tenofovir-based first-line regimen.¹¹ Additional investigations have included the examination of the risk of nevirapine-associated skin and liver reactions, and the risk of renal failure associated with tenofovir. The Namibian Technical Advisory Committee (TAC) for the treatment HIV/AIDS uses the data on adverse medicine reactions generated by the center to inform guideline revisions.

A comprehensive pharmacovigilance system (i.e., one that monitors product quality, adverse medicine reactions, and medication errors using a range of surveillance methods) should be a country's goal. Developing a comprehensive system from scratch is challenging. SPS developed an indicator-based pharmacovigilance assessment tool to facilitate the evaluation of the capacity of pharmacovigilance systems in a country. First, the tool facilitates the evaluation of the status of pharmacovigilance activities, country capacity and performance in ensuring patient safety, and effectiveness of health products. Secondly, the tool provides a starting point for determining the

¹¹ Nwokike J. et al. Using pharmacovigilance data to guide antiretroviral treatment guidelines decisions in Namibia. Paper presented at HIV/AIDS Implementers Meeting, June 10-14, 2009, Windhoek, Namibia; 2009.

key interventions that develop or strengthen the system.¹² This tool was used to assess pharmacovigilance systems in 46 sub-Saharan African countries and five Asian countries.^{13,14}

Enhancing Use of and Adherence to ARVs

Inappropriate dispensing or misuse (i.e., when a patient receives or takes the wrong medicine or dosage) reduces treatment effectiveness and can potentially cause antimicrobial resistance. Drug resistance limits the effectiveness of first-line regimens and leads to the need for second-line regimens that are more expensive and can cause more adverse reactions. In Kenya, a medication-use counseling checklist for ART serves as a job aid for dispensers to use when counseling their patients.¹⁵ The checklist helps the dispenser ensure that the patient and his or her representative adequately understand the proper use of the medicine, its storage, and the possible side effects. The national ART program adopted the checklist and rolled it out to all ART sites. Similar standard operating procedures (SOPs) for dispensing ART in Namibia were adopted by the Ministry of Health and Social Services (MoHSS) for nationwide use. Most importantly, anecdotal reports from patients indicated that they were satisfied with the quality of counseling provided during dispensing, and the providers use the communication skills they learned for ART for any medicine dispensing experience.



Figure 4. Ensuring confidentiality at the dispensing point in Ethiopia

Social stigma is a major deterrent to people seeking ART and treatment for other conditions, such as sexually transmitted infections and tuberculosis, so facilities need to assure confidentiality for patients and their records. Previously, large groups of people crowded around a pharmacy window to get their prescriptions; however, the noise and confusion made it impossible for pharmacists to give proper treatment instructions and made it likely that people would feel uncomfortable asking questions and could leave the pharmacy without understanding

¹² SPS. Indicator-based pharmacovigilance assessment tool: manual for conducting assessments in developing countries. Arlington, VA: MSH; 2009.

¹³ SPS. Safety of medicines in sub-Saharan Africa: assessment of pharmacovigilance systems and their performance. Arlington, VA: MSH; 2011.

¹⁴ SIAPS. Comparative analysis of pharmacovigilance systems in five Asian countries. Submitted to the US Agency for International Development by SIAPS. Arlington, VA: MSH; 2013.

¹⁵ Kagai D, Boruett P, Kimeu J, et al. Decentralization of ART pharmaceutical management in Kenya. Paper presented at XVII International AIDS Conference, Mexico City, August 3-8, 2008.

how to use their medications. Renovations of hundreds of dispensing structures in Kenya and Ethiopia included construction of confidential dispensing areas that help patients overcome stigma and benefit a wide variety of patients, not just those on ART (figure 4).

Adherence to ART is a major predictor of survival for HIV-positive individuals.^{16,17,18} Research in Ethiopia, Kenya, Rwanda, Tanzania, and Uganda showed that neither HIV and AIDS programs nor facilities had standardized definitions for treatment adherence, nor did they generally have rigorous procedures in place to track how well patients adhere to treatment or if they default on treatment altogether.^{19,20,21} Country teams tested the feasibility of collecting data and calculating indicators in 80 diverse facilities in East Africa. The teams then demonstrated the validity of a core set of indicators to predict weight gain and increased CD4 counts in newly treated patients.²² To maximize the chances of treatment success and minimize the development of drug resistance, ART programs need to be able to promptly identify and follow-up with patients who miss appointments. Yet in these settings, clinic appointment systems are haphazard—staff members record patients on arrival in a variety of registers, and typically, they have no way to determine who is expected and whether all expected patients have come each day.²³ After only two weeks of missed medication, however, resistance may already have developed.^{24,25}

In response, local teams led by staff from the national AIDS control programs in Kenya, Rwanda, Tanzania, and Uganda pilot-tested appointment systems to track patient attendance, reach out to missing patients, and monitor facility performance in adherence (e.g., figure 5). Participating ART clinics found that a minimally invasive, low-cost patient appointment and tracking system facilitated the management of their workload and promoted sustainable and consistent clinic attendance by HIV-positive patients.^{26,27,28}

¹⁶ El-Khatib Z, Katzenstein D, Marrone G, et al. Adherence to drug-refill is a useful early warning indicator of virologic and immunologic failure among HIV patients on first-line ART in South Africa. *PLoS One*. 2011; 6(3), e17518.

¹⁷ Fielden SJ, Rusch ML, Yip B, et al. Nonadherence increases the risk of hospitalization among HIV-infected antiretroviral naive patients started on HAART. *J Int Assoc Physicians AIDS Care (Chic)*. 2008; 7(5), 238-44.

¹⁸ Kitahata MM, Reed SD, Dillingham PW, et al. Pharmacy-based assessment of adherence to HAART predicts virologic and immunologic treatment response and clinical progression to AIDS and death. *Int J STD AIDS*. 2004; 15(12), 803-10.

¹⁹ Chalker JC, Andualem T, Gitau LN, et al. Measuring adherence to antiretroviral treatment in resource-poor settings: the feasibility of collecting routine data for key indicators. *BMC Health Serv Res*. 2010; 10, 43.

²⁰ Obua C, Gusdal A, Waako P, INRUD-IAA Project. Multiple ART programs create a dilemma for providers to monitor ARV adherence in Uganda. *Open AIDS J*. 2011; 5:17-24. Epub 2011 Mar 18.

²¹ Gusdal AK, Obua C, Andualem T, et al.; INRUD-IAA project. Voices on adherence to ART in Ethiopia and Uganda: a matter of choice or simply not an option? *AIDS Care*. 2009 Nov 21; (11):1381-7.

²² Ross-Degnan D, Pierre-Jacques M, Zhang F, et al. Measuring adherence to antiretroviral treatment in resource-poor settings: the clinical validity of key indicators. *BMC Health Serv Res*. 2010; 10, 42.

²³ Chalker J, Wagner A, Tomson G, et al. on behalf of INRUD-IAA. Appointment systems are essential for improving chronic disease care in resource-poor settings: learning from experiences with HIV patients in Africa. *Int Health*; first published online 2013 Jul 12; doi:10.1093/inthealth/ih013.

²⁴ Oyugi JH, Byakika-Tusiime J, Ragland K, et al. Treatment interruptions predict resistance in HIV-positive individuals purchasing fixed-dose combination antiretroviral therapy in Kampala, Uganda. *AIDS*. 2007; 21: 965-71.

²⁵ Parienti J-J, Das-Douglas M, Massari V, et al. Not all missed doses are the same: sustained NNRTI treatment interruptions predict HIV rebound at low-to-moderate adherence levels. *PLoS ONE*. 2008; 3: e2783. doi:10.1371/journal.pone.0002783.

²⁶ Mwatawala S, Sand D, Malele R, et al. Strengthening the appointment and tracking systems for patients on antiretroviral therapy in Tanzania: A optimizing adherence to ART as part of people-centered public health. *IJPCM*. 2012, 2(4):825-36; doi:10.5750/ijpcm.v2i4.302.

²⁷ Boruett P, Kagai D, Njogo S, et al. on behalf of INRUD-IAA. Facility-level intervention to improve attendance and adherence among patients on anti-retroviral treatment in Kenya: a quasi-experimental study using time series analysis. *BMC Health Serv Res*. 2013, 13:242.

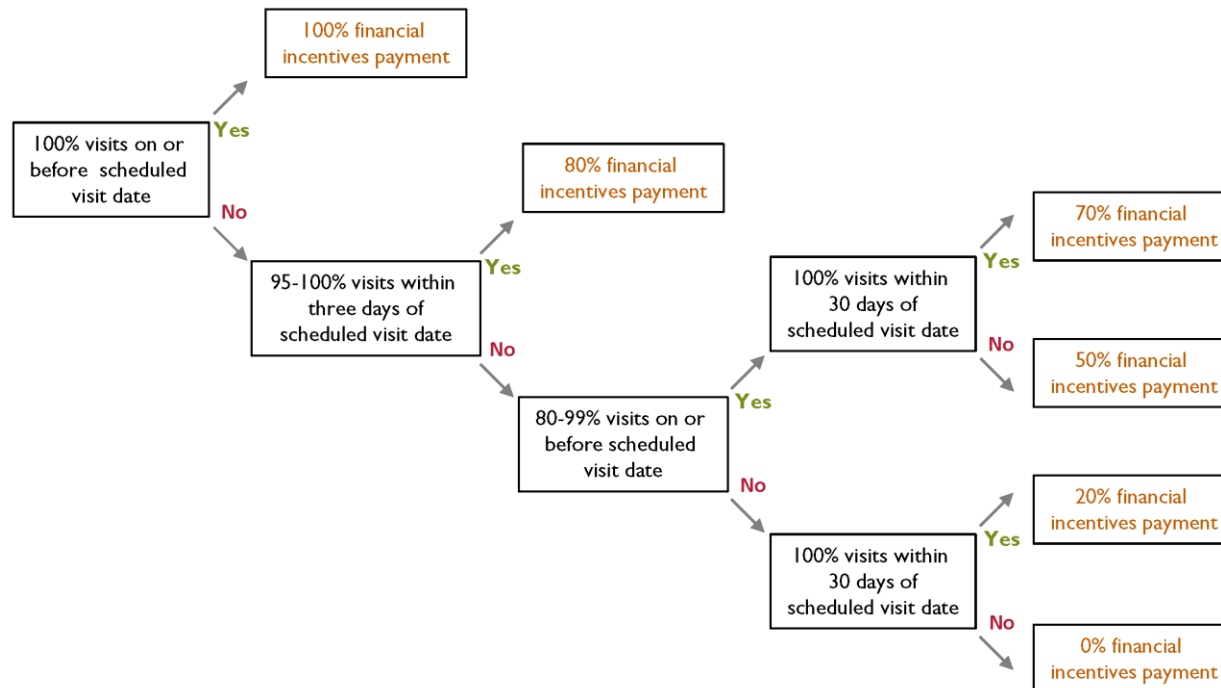


Figure 5. Algorithm to calculate the financial incentive to facilities in Rwanda that improve appointment keeping in ART patients.

Within the facility, the incentive amount was paid equally to participating staff regardless of their position or qualifications. Each eligible ART service staff member signed a contract with the study team, and this contract was endorsed by the facility administration.

Now that AIDS control programs look to the next level of care from the initial focus on scaling-up, they should emphasize adherence to ART. Increasing treatment literacy and determining local factors that affect treatment can promote patient adherence. Meanwhile, dissemination of patient- and facility-level indicators of adherence provides a systematic way to assess and compare adherence measures across facilities, programs, and countries, and to assess the impact of interventions to improve adherence. Resource-limited countries should consider standardizing and scaling up such systems in all ART settings and also using them to manage patients with other chronic diseases.^{14,29}

²⁸ Nyamusore J, Karema C, Hinda R, et al. Effects of patient tracking systems and providers incentives on patient appointment keeping in Rwanda. Paper presented at the Third International Conference for Improving Use of Medicines. Antalya, Turkey, November 14-18, 2011.

²⁹ Chalker J, Andualet T, Minzi O, et al. Monitoring adherence and defaulting for antiretroviral therapy in five East African countries: an urgent need for standards. *J Int Assoc Physicians AIDS Care (Chic)*. 2008; 7(4):193-9.

PHARMACEUTICAL WORKFORCE

Addressing Human Resource Shortages in the Pharmaceutical Sector for the Short and Long Terms

The shortages of health care providers in Africa are well documented. Short-term interventions such as task-shifting have helped ease the pressure on ART programs, but to expand and sustain access to ART, the next generation of interventions needs to focus more on long-term solutions. Severe shortages of critical health care personnel, including pharmaceutical professionals, call for a systematic approach to establish and strengthen the capacity of local training institutions to produce competent personnel in response to national needs.

At the launch of ART, Namibia had no institution training pharmacists; pharmacists were trained abroad or came from other countries to fill public service positions. As a result, Namibia relied heavily on pharmacists' assistants, but training programs had been unable to train enough candidates. Increasing the number of pharmacy staff available to manage and dispense ARVs was of paramount importance to the success of the country's ART program. In 2005, an assessment of and recommendations for the Namibian pharmaceutical sector were the first steps in identifying and implementing both short-term and long-term solutions to the pharmaceutical personnel shortage.³⁰ As an immediate solution, MoHSS increased the number of qualified pharmaceutical staff in public service by identifying vacancies and delineating needed responsibilities. A Namibian human resource firm recruited and hired new staff to fill government vacancies, and USAID provided financial support. The initiative doubled the number of government pharmaceutical staff, and eventually MoHSS absorbed them into the public sector.³¹ This collaboration created a new mechanism to help the government quickly fill urgent personnel needs in the public pharmaceutical sector, while allowing it to gradually absorb the positions into its existing structure.



Figure 6. A pharmacist assistant trained at the Namibia National Health Training Centre

³⁰ MSH. Human capacity development assessment for public sector pharmaceutical services in Namibia: Strategies to scale up HIV/AIDS programs and ART therapy. Submitted to the US Agency for International Development by the Rational Pharmaceutical Management Plus Program and the Management and Leadership Program. Arlington, VA: MSH; 2006.

³¹ Tjipura-Tjiho D, Mabirizi D, Lazell K, et al. A partnership model to improve human resource capacity to deliver pharmaceutical services in Namibia. Paper presented at the HIV/AIDS Implementers Meeting, June 16-18, 2007, Kigali, Rwanda.

To address the long-term training issues, Namibian stakeholders expanded the institutional capacity of the National Health Training Centre by renovating classrooms and offices, providing tutors and consultants, revising the pharmacists' assistant training curriculum, and developing standards and qualifications for the pharmacists' assistant course, which paved the way for national accreditation (figure 6). Through these interventions, the National Health Training Centre increased its capacity for training pharmacists' assistants by 300%.³² The graduating pharmacists' assistants quickly engaged in government efforts to decentralize ART services and enhance access to ART in remote parts of the country. Another long-term response was to help the University of Namibia develop a bachelor of pharmacy program—49 students were enrolled in less than two years. In Namibia, efforts to increase the number of skilled workers helped increase the pharmacists-to-population ratio from 0.4/100,000 in 2004 to 2/100,000 in 2010—a 400% increase. “Initial results of these activities include critical central posts being filled, vacancy rates reduced by 50%, four regional posts were filled, and 11 treatment facilities received pharmacists and pharmacist assistants.”³³

The National Health Training Centre has indeed become a cornerstone institution to train health care providers throughout Namibia. It plays a vital role, particularly in the battle against HIV/AIDS and tuberculosis.

—US Ambassador to Namibia, G. Dennise Mathieu

Many countries have addressed the shortage of people trained in pharmacy by providing pre-service or in-service training to other cadres, such as nurses or clinical officers (figure 7).

Changing in-service and pre-service training curricula to include or strengthen pharmaceutical and ART management can be a challenge because of the various stakeholders involved, but countries have been successful and guidelines exist.³⁴ Strengthening existing pre-service and in-service training programs is the best way to ensure adequate and sustained availability of health workers capable of managing and providing ART services.

³² SPS. Strengthening Pharmaceutical Systems Program Final Report: 2007–2012. Submitted to the US Agency for International Development SPS. Arlington, VA: MSH; 2013.

³³ USAID/Namibia: Strengthening Pharmaceutical Systems and Supply Chain Management Systems Evaluation; 2010. Pg. 9.

³⁴ SIAPS. Revising preservice curriculum to incorporate rational medicine use topics: a guide. Submitted to the US Agency for International Development by SIAPS. Arlington, VA: MSH; 2013.

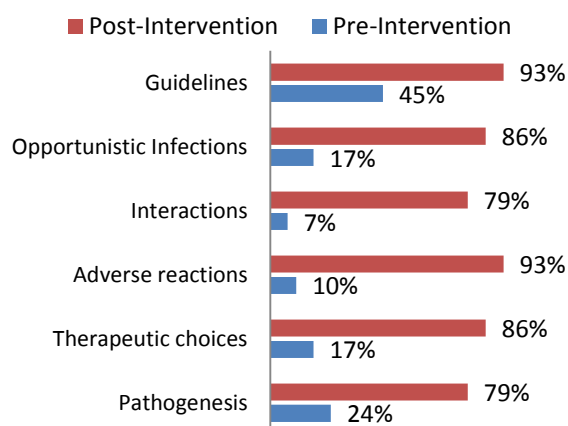


Figure 7. Improvement of knowledge of pharmaceutical services for HIV and AIDS

Building the capacity of nurses who provide HIV and AIDS-related pharmaceutical services in rural Namibia through a 10-month in-service pharmacotherapy program.

To address the lack of staff capacity at ART sites in Kenya, development partners supported curriculum reviews for middle- and tertiary-level training institutions and the rollout of in-service training courses covering pharmaceutical management and pharmaceutical care for patients on ART. In addition, the Kenya Pharmaceutical Association collaborated with other professional associations to develop a series of one-day courses on ART practices, targeting over 1,000 practitioners in the private and community sectors.³⁵ Private sector practitioners are often ignored and do not have updated knowledge on treatment guidelines.

Other approaches have been to use a policy or legislative solution. For example, in South Africa, changes to the legislative requirements related to which cadres can prescribe and dispense increased access when nurses were approved to provide ART.³⁶

Severe shortages of critical health care personnel, including pharmaceutical staff, call for a systematic approach to establish and strengthen the capacity of local training institutions to produce competent health care personnel in response to national needs. Pharmaceutical sector human resource assessments provide a clear picture of a country's context and make it easier to prioritize solutions.³⁷

³⁵ Kusu N, Shah H, Boruett P, Gitau L, Ouma C, Wangai M. Using professional societies to promote rational use of antiretrovirals through continuous education in Kenya's private and community health sector. Paper presented at the XVIII International AIDS Conference, July 18-23, 2010, Vienna.

³⁶ SIAPS. Systems for improved access to pharmaceutical services annual report: project year 2, October 2012–September 2013. Submitted to the US Agency for International Development by SIAPS. Arlington, VA: MSH; 2013.

³⁷ MSH. Human resources management and capacity development. In: MSH. MDS-3: managing access to medicines and health technologies. Sterling, VA: Kumarian Press; 2013.

ENHANCING ART LOGISTICS AND INFORMATION SYSTEMS

Information for timely and informed decision making is critical for successfully ensuring uninterrupted availability of ARVs. Improving pharmaceutical sector information systems requires integrating pharmaceutical data collection, processing, and presenting information to facilitate evidence-based decision making for the efficient management of pharmaceutical commodities and pharmaceutical services.

Creating a Pharmaceutical Information System that Supports Overall Health System Planning and Decision Making

A pharmaceutical management information system should include varied data sources from the entire pharmaceutical sector (not just procurement and inventory management–related activities); patient-specific data in addition to logistics management information system product-centered data; and the ability to triangulate consumption data with clinical and patient-specific data. Lack of patient data is the most common limitation and results in inaccurate projections and therefore ARV shortages or wastage. Ultimately, pharmaceutical sector data should feed into a country's overall health management information system; however, establishing this link remains a challenge in many countries.

To significantly improve HIV and AIDS program performance and planning, focus should be on strengthening pharmaceutical management information systems that produce key data for program planners. Kenya has harmonized information on multiple commodity streams, thus allowing program managers to evaluate regular stock status reports and take action before a stock-out emergency (figure 8).

Swaziland's MoH worked with partners to design a management information system for all levels of the health care system to support short- and long-term supply chain decisions regarding HIV commodities³⁸—

- A data management unit was established to collect, collate, analyze, and present information to a newly formed technical working group for supply chain decision making.
- The information system was revised to link facilities with the Central Medical Store through a maximum-minimum inventory control system.
- Standardized tools for reporting and requisition were designed, printed, and distributed to more than 100 ART facilities across the country.
- Over 200 staff members at all ART sites were trained to use the information system tools, and they received continuous supportive supervision.

³⁸ Shiferaw G. Using data to strengthen supply chain performance for HIV and AIDS commodities in Swaziland. Paper presented at the Sixth Global Health Supply Chain Summit, November 18-20, 2013, Addis Ababa, Ethiopia.

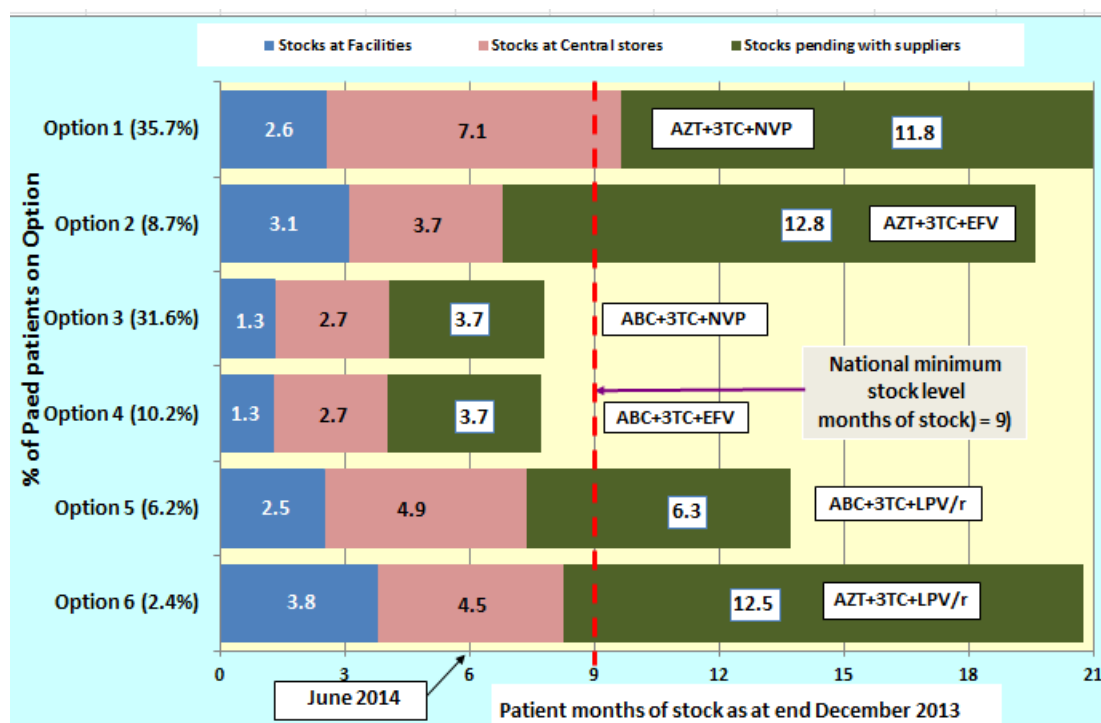


Figure 8. Pediatric ARV stock status at the Kenya Medical Supplies Authority and Kenya Pharma based on patient months-of-stock: December 2013³⁹

Although mobilizing enough health workers at the facilities to take on the additional responsibilities has been difficult, workers are now better equipped to assess their stock levels and place appropriate orders. As a result, Swaziland facilities have improved their reporting rates from 56% to 95%; they have achieved 100% stock availability for critical ARVs; and ARV order fill rates have reached 100%. In addition, MoH's use of the information has resulted in a savings of USD 6.25 million from unnecessary procurement and USD 700,000 through the averted expiration of stavudine.⁴⁰

Designing User-Friendly Tools that Facilitate Decision Making

A challenge at ART sites has been collecting timely and accurate health data for strategic planning using a paper-based health records system. To increase access to reliable ART information, the Rational Pharmaceutical Management Plus Program developed the ART Dispensing Tool in 2005 to maintain the patient profile, history of medicines dispensed, and other patient information, such as appointments. Users of the tool can also easily generate reports to meet multiple reporting requirements, which was a problem as countries were scaled up ART under different donors. Although the tool started as an ART-specific solution, its functionality was broadened to support many diseases, and it has been adapted to include country-specific essential medicine lists—it is now known as the Electronic Dispensing Tool (EDT). The EDT in

³⁹ MoH, NASCOP Unit. Kenya anti-retroviral medicines (ARVs) stock situation – December 2013 Final. Nairobi: NASCOP.

⁴⁰ Ibid.

use in more than 300 health facilities providing ART in Ethiopia, Kenya, Morocco, and Namibia, and it is expanding to Cameroon, DRC, and Togo (figure 9). A mobile version has also been developed for settings without access to computers.⁴¹

“[EDT] has reduced our workload through quicker dispensing, affording us enough counseling time with each patient,”

—Wendy Chagwinya, pharmacist’s assistant at Mariental Hospital, Namibia.

ART sites in Kenya reported the EDT’s greatest benefits as time saved in preparing reports and estimating reorder quantities and improved accuracy, resulting in negligible stock-outs. Resulting data contribute to calculating patient scale-up trends and regimen proportions, therapeutic value analysis, and ABC analysis, which is a way to rank medicines by value; for example, the ABC value analysis using consumption data in Kenya showed that after substituting generics of nevirapine from the branded version, its value shifted significantly from 40% of the ARV budget in 2005 to 9%.⁴² In Ethiopia, data from the tool identified early side effects associated with stavudine 40 mg, which resulted in replacement with the 30 mg formulation.⁴³



Figure 9. The EDT in use in ART health facilities

Facilities can also use EDT to monitor WHO early warning indicators. A key achievement of the implementation of this tool was empowering facility staff to generate and analyze data, and then use their own data to identify program weaknesses and take action to address shortcomings—not just report the data upward.

Another tool that was originally designed for ART data at hospital and district levels is an integrated computerized pharmaceutical supply management tool called RxSolution. It manages orders, receipts, stock levels, and dispensing at more than 300 sites in Lesotho, Namibia, South

⁴¹ Kunda M, D Pereko, A Blom, et al. Using mobile technology to strengthen HIV/AIDS management in remote areas. Paper presented at the Third International Conference for Improving Use of Medicines. Antalya, Turkey, November 14-18, 2011.

⁴² MSH. Analyzing and controlling pharmaceutical expenditures. In: MSH. MDS-3: managing access to medicines and health technologies. Sterling, VA: Kumarian Press; 2013.

⁴³ Kebede G, Laike A, Selassie G, Mekonnen N. Strengthening Pharmaceutical Management Information Systems at ART Pharmacies. Paper presented at the Global Health Council Conference, May 26-30, 2009.

Africa, Swaziland, and Uganda. Use of RxSolution has contributed to significant improvements in ARV and essential medicines availability, improved inventory management, and better patient care. For example, in Free State Province in South Africa, the tool facilitates the automated generation of orders based on consumption data. In Limpopo Province, RxSolution helps manage direct deliveries for ARVs and oncology agents to over 40 hospitals.⁴⁴

In addition, Swaziland's Ministry of Health and Social Welfare implemented RxSolution as a way to strengthen its pharmaceutical information and supply management system. As a result, the Global Fund released funds to procure ARVs and other medicines that it had withheld from Swaziland, pending such strengthening efforts. Public and private facilities there now generate reports to monitor patient management, stock levels, and consumption trends, and none has reported stock-outs.⁴⁵

Although it has been over a decade since ART became accessible in resource-limited countries, most health information systems are still lagging behind. ART programs have made progress in collecting, reporting, and using data, but in many cases, monthly reports are incomplete and inaccurate, making it difficult to produce useful forecasts. Countries need to review their data collection tools and systems, and consider using electronic tools or other mechanisms as feasible to ensure that information systems accurately capture the needed information at the point of service and transmit it to the central level for analysis and use in decision making. Accurate quantification and forecasting for ARVs and other HIV-related products not only decreases stock-outs, but also provides the evidence needed to advocate for and mobilize funding for the procurement of ARVs.

⁴⁴ SIAPS. Systems for Improved Access to Pharmaceutical Services Annual Report: Project Year 2, October 2012–September 2013. Submitted to the US Agency for International Development by SIAPS. Arlington, VA: MSH; 2013.

⁴⁵ Sallet J-P, Sigl E, Sibiyi T, et al. Securing Global Fund allocation by strengthening medicines supply management systems: the Swaziland experience. Paper presented at South African Association of Hospital & Institutional Pharmacists, KwaZuluNatal, South Africa, March 8-10, 2007.

FINANCING FOR ART PROGRAMS

Pharmaceutical financing broadly covers resource mobilization, resource pooling, payment and purchasing. Traditionally, financing has been perceived as relating to funding pharmaceutical purchases, and initiatives such as the Global Fund and PEPFAR focus heavily on such funding; however, even countries with adequate funds to procure medicines cannot always manage the flow of funds and assure product availability. To continuously increase efficiency, countries should conduct analyses to improve decisions regarding cost containment and options for mobilizing financing through gap analysis.

Controlling Costs and Maximizing Financial Efficiency

Accurately quantifying needed ARVs has been a major factor to successfully scaling up ART and ensuring uninterrupted access to ARVs. Many countries, such as Kenya, Namibia, and Rwanda, established national committees to track and coordinate ARV quantification and procurement activities and develop consensus on assumptions. Accurate quantification does not only prevent stock-outs of lifesaving medicines, it saves money; for example, Swaziland saved USD 6.1 million in the 2012–13 budget year and USD 399,312 in the 2013–14 budget year for HIV commodities by undertaking continuous and evidence-based quantification, and the procurement budgets for ART and reproductive health commodities were reduced by 6.4% and 69.2%, respectively.⁴⁶ By conducting cost analyses and increasing the efficiency of procurement systems, ART programs can control costs and maintain availability of ARVs as illustrated in South Africa and the Dominican Republic.

In South Africa, development partners created a pharmaco-economic model using international benchmarking techniques that illustrated how the government could save money in procurement by selecting a safer ART regimen. Through use of the modeling, South Africa saved about 53% on its next ARV tender, and saved USD 32 million in its 2013 procurement.⁴⁷ Continued use of the modeling has led to the introduction of fixed-dose combinations and the revision of the national essential medicine list based on analyzing tender prices and identifying other procurement inefficiencies.

The Dominican Republic has one of the highest rates of HIV/AIDS infection in the region. The Global Fund had provided the majority of financing to purchase its lifesaving ARVs; however, in the last few years, Global Fund disbursements for ARVs decreased, and the government was unable to cover the gap for 2013, valued at USD 3.8 million. Actions taken to close the gap included changing to a new ARV supplier, securing unused resources on deposit with the previous supplier, and for the first time, MoH adding the purchase of ARVs to its budget. These

⁴⁶ SIAPS. Systems for Improved Access to Pharmaceutical Services Annual Report: Project Year 2, October 2012–September 2013. Submitted to the US Agency for International Development by SIAPS. Arlington, VA: MSH; 2013.

⁴⁷ Steele G, Pharasi B, Sallet JP. Application of an international reference price list to national medicines procurement tenders. Paper presented at the Third International Conference for Improving Use of Medicines. Antalya, Turkey, November 14–18, 2011.

strategies not only covered the USD 3.8 million gap, but also generated a surplus for the procurement of diagnostic materials. As a result, availability of ARVs increased significantly.⁴⁸

Addressing the Cost Implications of ART Changes to Second-Line Medicines

Lower ARV prices, influenced by the introduction of generic products, have made scale-up of HIV and AIDS programs feasible in low-income settings. Because second-line treatments are mostly innovator products, however, they are usually many times more expensive than first-line regimens, monitoring switches in ART regimens is necessary not only to assure that cases are being managed appropriately at the facility, but also to plan and allocate resources for second-line treatment at facility and national level.

ART programs and ultimately other priority health programs can use data from the pharmaceutical management information system to identify trends in treatment switching, evaluate the clinical appropriateness of the practice, and take corrective actions as needed. At the national level, these trends inform review of national standard treatment guidelines. In addition, programs can use the information to budget for second-line medicines. For example, a tertiary ART site in Namibia used data from the EDT to determine that its one-year switching rate in 2008 was 3.7%.⁴⁹ The site now has a benchmark for future comparison and the data needed to estimate the allocation for second-line medicines. Data from 613 health facilities in Ethiopia showed that clinicians were putting an unacceptably large percentage of new patients on stavudine-based regimens as opposed to the recommended tenofovir-based regimens. As a result, the national ART technical working group recommended reducing stavudine procurement and notified facilities to stop providing stavudine-based regimens.⁵⁰

Managers should review ART patterns to determine lack of compliance to ART guidelines and enact interventions to boost appropriate use of ARVs. Without such analysis, Ethiopia would have most likely continued to procure stavudine based on consumption patterns, resulting in higher rates of adverse effects among ART patients.

An analysis of the consumption data from the Gauteng Provincial Medical Supplies Depot in South Africa identified percentages of patients on second- and first-line ART in 2011.⁵¹ Only 49.4% of switches to the second-line regimen were in compliance with the guidelines. This low percentage was partly because of a lack of systematic adherence assessment (47.4%). The absence of second viral load testing was responsible for 32.1% of the non-compliance, implying switching was done without supporting laboratory evidence. Among the patients switched for regimen failure, only 46.7% were switched in compliance with the guidelines. Based on 2013 government contract prices, the lack of compliance cost an extra R 8.79 million (~USD 795,000)

⁴⁸ SIAPS. Systems for Improved Access to Pharmaceutical Services Annual Report: Project Year 2, October 2012–September 2013. Submitted to the US Agency for International Development by SIAPS. Arlington, VA: MSH; 2013.

⁴⁹ Rational Pharmaceutical Management Plus Program. Unpublished data.

⁵⁰ SIAPS. Strengthening Pharmaceutical Systems Program Annual Report: Project Year 1, October 2011–September 2012. Submitted to the US Agency for International Development by SIAPS. Arlington, VA: MSH; 2013.

⁵¹ Berrada S, Mkandawire T, Kamungoma-Dada I, Njuho P, Thipa N, Pinini Z, et al. Financial implications of poor compliance with standard treatment guidelines for switching patients onto second-line antiretroviral therapy. Paper presented at South Africa Association of Hospital and Institutional Pharmacists' 28th Annual Conference 2014, March 6-9, 2014, Drakensberg, South Africa.

per year per 10,000 patients on second-line ART. The data analyses have provided the province with the information needed to improve treatment practices.

New HIV-related products including fixed-dose combinations continue to hit the market; however, countries need to optimize the number of treatments with a target of getting 80% of patients on the recommended first-line regimens. Policy makers need to review compliance to treatment guidelines regularly and use medication reviews to ensure that clinicians are following them. In addition, early warning indicators of HIV medicine/drug-resistance should be monitored and used in revising treatment recommendations. New WHO guidelines call for a number of treatment changes and a larger population eligible for ART.⁵² Countries need to consider treatment options carefully and plan for this transition. Carrying out changes in treatment guidelines should be staggered to minimize waste and assure an effective transition to a new regimen. Maintaining the majority of patients on the fewest regimens not only simplifies the supply chain and makes it more predictable, but also increases appropriate use and cuts costs.⁵³

⁵² WHO. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. Geneva: WHO; 2013.

⁵³ MSH. Managing medicine selection. In: MSH. MDS-3: managing access to medicines and health technologies. Sterling, VA: Kumarian Press; 2013.

LEADERSHIP AND GOVERNANCE IN THE DELIVERY OF ART

“Good governance is increasingly understood as necessary for improving access to medicines and contributing to health systems strengthening.”⁵⁴ Governance issues are rarely specific only to one system component or one ministry or only to the public or private sector. Stakeholders include industry, suppliers, professional associations, media, health care providers and consumers, and regulators. Addressing problems may require collaborative action by multiple groups, which can be a challenge. Although leadership and governance in the sector may be improved in many ways,⁵⁵ country ownership and involvement of impartial stakeholders are critical components.⁵⁶ Improving leadership, governance, and accountability requires establishing transparent management systems grounded in policies based on best practices; legislation supported by the rule of law; organizational structures able to exercise appropriate decision making, authority, and oversight; and human resource management systems that promote effective performance and ethical practices.⁵⁵

Standardizing Practices through Standard Operating Procedures in Kenya

An essential component of managing an ART program at the facility level is establishing SOPs for all departments that contribute to ART care, including the pharmacy and laboratory. SOPs act as a standard for defining and monitoring the quality of service delivery and facilitating training efforts; they are critical to the successful, rapid scale-up of safe and effective ART. Few public institutions in developing countries, however, had pharmacy and laboratory SOPs for existing services—so examples for ART program implementers to draw upon were lacking. In 2003, the MoH and partners developed an initiative for incorporating ARVs into the existing health care system in Coast Province. A key element of this initiative was the collaborative and inclusive approach to building local ownership and capacity for introducing and then scaling up access to ART, including the development of SOPs for the pharmacy and laboratory to support ART services.⁵⁷ The resulting products were institutionalized by the Government of Kenya for all ART facilities and were widely distributed and adapted by other nascent ART programs in Ethiopia, Namibia, and Zambia. Once facilities embrace the use of SOPs for ART, it is easy to adapt and enhance them to cover other health care programs, and indeed, many SOPs developed for ART describe general procedures.

⁵⁴ WHO. The world medicines situation, 3rd ed. Geneva: WHO; 2011. p. 1.

⁵⁵ SPS. Pharmaceuticals and the public interest: the importance of good governance. Submitted to the US Agency for International Development by SPS. Arlington, VA: MSH. 2011.

⁵⁶ Kohler JC, Mackey TK, Ovtcharenko N. Why the MDGs need good governance in pharmaceutical systems to promote global health. *BMC Public Health*. 2014; 14:63.

⁵⁷ Walkowiak H, Olwande C, Baya K, Jao JM. Scaling up access to ART in resource-limited settings: integrating ART programs into existing pharmaceutical management systems to support sustainable quality care in Mombasa, Kenya. Paper presented at the XV International AIDS Conference, July 11-16, 2004, Bangkok.

Strengthening Namibia's Capacity to Quickly Register Pharmaceuticals and Get Them on the Market

Namibia's pharmaceutical registration process was stymied by a growing demand for ARVs, resulting in a huge backlog of registration applications for medicines awaiting marketing approval; in September 2004, about 1,000 applications were outstanding. At that time, 49 ARVs were on the market, but the delay was preventing access to valuable fixed-dose combinations and pediatric products. A key intervention that streamlined the registration process was a policy change that prioritized ARVs for registration and created a proxy evaluation process to quickly accept products already registered in International Conference on Harmonization countries and other stringent regulatory authorities, including South Africa. A medicine registration database, PharmaDex, was put in place to manage the dossier review process and facilitate data analysis. In the first year of the intervention, 1,392 applications for new medicines were evaluated. Of those, 14 ARVs were reviewed and approved, including much-needed pediatric dosage forms, fixed-dose combinations, and generic products that helped lower prices.⁵⁸ In addition, a new website allowed for increased transparency of pharmaceutical regulatory activities. Streamlined registration reduced the average time to register a medicine from 13 to 4 months, increased the number of registered ARVs by 30%, and increased the number of multisource generic ARVs by more than 70%.⁵⁹ These interventions increased the number of ARVs available for people living with HIV/AIDS in Namibia.

⁵⁸ Pereko D, Nwokike J. Improving the availability of ARVs in Namibia by using policy change to streamline the drug registration process. Paper presented at the XVI International AIDS Conference, August 13-18, 2006, Toronto.

⁵⁹ SPS. Strengthening Pharmaceutical Systems Program Final Report: 2007–2012. Submitted to the US Agency for International Development by SPS. Arlington, VA: MSH; 2013.

RECOMMENDATIONS AND CONCLUSIONS

The population of patients on ART in low- and middle-income countries has increased to 9.7 million with 61% coverage.⁶⁰ The following are recommendations on how to continue to strengthen pharmaceutical systems to sustain the current number of people on treatment and to increase access and coverage—

Coordination of ART Services

- Enhance coordination between the entities responsible for managing HIV and AIDS service delivery within the leadership of MoH technical departments to include supply chain teams (quantification and procurement planning for ARVs).

Information Systems and Evidence for Decision Making

- Improve patient and commodity data collection tools, data analysis, and the use of data for decision making in quantification, forecasting, supply planning, and procurement of ARVs; consider the use of electronic pharmacy/dispensing tools and other tools to ensure the collection and timely transmission of accurate data related to ART services.
- Develop and institutionalize standard indicators for monitoring health outcomes of ART including adherence, patient retention, loss to follow-up, appointment keeping, morbidity/mortality trends.
- Monitor and minimize the risk of HIV medicine resistance by implementing the WHO recommended strategy for monitoring early-warning indicators of HIV drug resistance.

Service Delivery

- Integrate ART into the existing service delivery system (outpatient and inpatient services).
- Analyze facility-level service patterns to enhance the use of evidence in decision making and assure that prescription and dispensing practices comply with guidelines. Regular treatment reviews will ensure that patients are on as few regimens as possible that minimize pill burden and ensure optimal adherence.
- Standardize and monitor treatment and dispensing practices across public and private sectors.
- Strengthen supportive supervision of health facilities

⁶⁰ WHO/UNICEF/UNAIDS. Progress in people receiving treatment in low and middle income countries and percent of eligible receiving antiretroviral treatment. (Update from 2013 Global AIDS response progress report); 2013. Available from: <http://www.who.int/hiv/data/ARTmap2013.png?ua=1>

- Develop centers of excellence in the care of patients on ART to serve as platforms for sharing best practices, but also to serve as referral centers.

Human and Institutional Capacity

- Develop long-term strategies for incorporating pharmaceutical and HIV management in pre- and in-service training curricula to increase the number and scope of health workers who manage HIV and AIDS as part of an integrated service.

Funding for ARVs

- Address the dwindling donor funding for HIV and AIDS programs by carrying out strategies to increase local funding and identify funding gaps.
- Increase transparency in ARV procurement and postmarket surveillance in public and private sectors to eliminate counterfeit or substandard ARVs.

Regulatory Systems

- Strengthen ARV regulatory systems by improving registration, pharmacovigilance and inspection.

Continuing the health system response to HIV and AIDS in this post scale-up era requires a shift from a fragmented approach that aims to get as many people on treatment as quickly as possible to a holistic, coordinated health system that is based on the six building blocks.⁶¹ We have already seen how interventions and tools that were developed as part of the initial drive to scale up ART have been expanded and adapted to include other areas of public health—not only in clinical care, but in pharmaceutical management. Indeed, the management of HIV and AIDS has evolved into a structured chronic disease program, like diabetes or cardiovascular disease, which will require lifelong access and adherence to medicine-based treatment.⁶² In the pharmaceutical sector, the next challenges involve integrating HIV and AIDS into the overall health system, creating and using reliable ART data, monitoring treatment adherence, harmonizing parallel pharmaceutical supply chains, and using the profound achievements of HIV and AIDS programming to strengthen the health system for everyone.

⁶¹ MSH. Reversing the AIDS epidemic through third-generation health systems: a call to action. Cambridge, MA: MSH; 2009.

⁶² Deeks SG, SR Lewin, DV Havlir. The end of AIDS: HIV infection as a chronic disease. *Lancet*. 2013; 382 (9903): 1525-33. doi:10.1016/S0140-6736(13)61809-7.